

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/199,043 11/10/98 CHEE

M A-66828-1700

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EXAMINER

MARSCHEL, A

| ART UNIT | PAPER NUMBER |
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1631

26

DATE MAILED:

10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|-------------------------------|-----------------------------|
| Application No. 09/189,543 | Applicant(s) Chee et al. |
| Examiner Ardin Marschel | Art Unit 1631 |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jul 16, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 and 15-31 is/are pending in the application.

4a) ~~None of the above~~ Claim(s) 8-14 have been canceled

5) Claim(s) 17 is/are allowed.

6) Claim(s) 1-7, 15, 16, and 18-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) ~~Exhibit(s)~~ (3 sheets)

20) Other: _____

Applicants' arguments, filed 7/16/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-5, 7, 15, 16, 18-22, and 25-31 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Walt et al. (P/N 6,023,540).

This rejection is reiterated and maintained from the previous office action, mailed 4/9/01. Applicants argue that Walt et al. is silent regarding identifier binding ligands. In response applicants have not argued the specifically pointed to binding ligand teaching in column 11, lines 1-14, of the

reference. Here fluorescent dyes bind to the microspheres for subsequent identification. Binding cannot occur in a vacuum. These dyes must bind somewhere, and to something, on the microspheres. Binding is reasonably interpreted as being performed wherein two entities, normally called ligands, bind to each other. Such binding moieties are thus responsible for the dye binding which is then utilized for identification. As noted in the previous office action the binding reaction changes the optical response of the microspheres and clearly, as previously noted, is an identifier/decoder entity as item "64", for example. Thus, the binding moieties which bind the identifier dyes are clearly identifier binding ligands as required in the instant claims.

Claims 1, 4, 5, 7, 18, 20, 30, and 31 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Ekins et al. (P/N 5,516,635).

This rejection is reiterated and maintained from the previous office action, mailed 4/9/01. Applicants argue that Ekins et al. requires a spot "binding" and random movement to the binding surface as distinct from the instant invention which requires random distribution onto a surface. In response it is firstly noted that the microspheres of Ekins et al. bind to the surface to form an array of microspheres on the surface. This is also performed in the instant invention. It is also noted that

the previously set forth NEW MATTER rejection has been withdrawn because applicants persuasively argued that the surface distribution of microspheres may be either random or patterned. This is reasonably interpreted that the surface distribution of microspheres may occur with any distribution characteristic because random or patterned covers all possible surface distributions of such microspheres. Thus the attachment of microspheres on the surface in Ekins et al., as occurring via binding, is random as the microspheres randomly approach the surface and bind randomly to binding entities on the surface. This binding may also be interpreted as being patterned in that the binding pattern of the microspheres is governed by the specific locations of binding entities on the surface which will be either specifically patterned or random regarding their locations depending on how they were originally disposed on the surface. Again either patterned or random microsphere array distributions are present in the Ekins et al. array practice. Applicants again argue the absence of identifier binding ligands on the Ekins et al. microspheres. In response these microspheres cannot bind labels without binding sites thereon which thus result in identification of the microspheres. Thus identifier binding ligands must be present on the microspheres as similarly noted in the above rejection based on Walt et al. Again binding cannot occur in a vacuum but must occur between entities normally

termed ligands in the art.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-7, 18, 20, and 22-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ekins et al. (P/N 5,516,635); taken in view of Matthews et al.

This rejection is reiterated and maintained from the previous office action, mailed 4/9/01. Applicants argue that Ekins et al. does not provide motivation to employ binding or decoder ligands as an identifier. This allegation is not agreed with. Ekins et al. was noted in the previous office action, mailed 4/9/01, as describing the usage of enzyme markers or labels and detectable labels and Matthews et al. is a review of

such entities. Such generic suggestion in Ekins et al. is reasonably suggestion to utilize a review such as Matthews et al. for labels and/or marker practice. It is noted that Matthews et al. was specifically discussed in the previous office action, mailed 4/9/01, as suggesting and motivating a variety of such labels and markers in various assays in the art. Clearly, the assay of Ekins et al. is in the art and utilizes equivalent labels and markers. Applicants then argue that Ekins et al. does not teach or suggest a random distribution of microspheres onto a surface. This has been responded to above already in that either a random or patterned distribution of microspheres on a surface is described by Ekins et al. depending merely how one wishes to characterize the binding activity that occurs in the Ekins et al. invention. Applicants focus on random distribution is confusing in that applicants themselves have argued that patterned or random distributions are both included within the metes and bounds of the instant invention.

It is acknowledged that the following applications have been considered as indicated in the IDS, filed 9/24/01: 09/344,526; 09/315,584; 09/256,943; 09/606,369; 09/151,877; 09/450,829; 08/851,203; and 09/187,289. Certain serial numbers in said IDS are not listed above because they are already of record as having been considered. However, the files for 09/748,706; 09/786,896; 09/816,651; and 09/840,012 were unavailable for consideration at

this time due to being in a new application processing.

Claim 17 is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 28, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER